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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,235	11/01/2000	Raghubir S. Bhullar	RDID 0030 US	2645

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

0213

Office Action Summary

Application No.

09/704,235

Applicant(s)

BHULLAR ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. Applicant's amendment of September 18, 2003 does not render the application allowable.

Response to Arguments

2. Applicant's arguments have been considered but are moot in view of the new grounds of rejection.

3. With respect to the rejection of claims 1-9, 12, 13, and 16-19 under 35 U.S.C. 102(e) as being clearly anticipated by Hodges et al., Applicant appears to argue that the new limitation of "a cover positioned on the substrate" in claims 1 and 13 should be interpreted to limit contact between the cover and substrate to direct physical contact. However, claim 12 provides for "an adhesive positioned *between* the cover and the substrate [emphasis added]." Thus, the claim language itself indicates a broader interpretation than argued for this limitation. Similarly for the rejection of claim 11 under 35 U.S.C. 103(a) as being obvious over Hodges et al.

Status of the Rejections Pending since the Office action of March 19, 2003

4. The rejection of claims 1-19 under 35 U.S.C. 112, first paragraph, is withdrawn.
5. The rejection of claims 20 and 21 under 35 U.S.C. 112, first paragraph, is withdrawn.
6. The rejection of claims 1-3, 9, 10, and 12-15 under 35 U.S.C. 102(b) as being anticipated by Charlton et al. is withdrawn.
7. The rejection of claims 1-9, 12, 13, and 16-19 under 35 U.S.C. 102(e) as being clearly anticipated by Hodges et al. is restated below with modifications in light of Applicant's amendment.
8. The rejection of claims 1-3, 9, 10, and 12-15 under 35 U.S.C. 102(e) as being clearly anticipated by Uenoyama et al. is withdrawn.
9. The rejection of claims 1 and 9-11 under 35 U.S.C. 103(a) as being obvious over Bhullar et al. (US 6,619,719 B1) is withdrawn.
10. The rejection of claims 2, 3, 7, and 13 under 35 U.S.C. 103(a) as being obvious over Bhullar et al. as modified by Uenoyama et al. and Bhullar (EP 1098000 A2) is withdrawn.

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11. The rejection of claims 1-3 and 9-13 under 35 U.S.C. 103(a) as being obvious over Bhullar (EP 1098000 A2) is withdrawn.

12. The rejection of claim 11 under 35 U.S.C. 103(a) as being obvious over Charlton et al. is withdrawn.

13. The rejection of claim 11 under 35 U.S.C. 103(a) as being obvious over Hodges et al. is restated below with modifications in light of Applicant's amendment.

14. The rejection of claim 12 under 35 U.S.C. 103(a) as being obvious over Bhullar et al. (US 6,619,719 B1) as modified by Uenoyama et al. and Charlton et al. is withdrawn.

Drawings

15. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the non-embossed or non-preformed channels, which are formed by surface irregularities and structural defects in the cover and the substrate, must be shown or the features canceled from the claims. No new matter should be entered.

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A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The claims require the channel to be non-embossed or non-preformed. According to Applicant's amendment (and specification) the channels are formed from surface irregularities in the cover and substrate and also variations in the thickness of the reagent. The figures clearly show embossed and preformed channels. Most especially Figures 3-5, which show several different views of a uniform and symmetrical capillary channel 40 and gaps 62 and 64.

Claim Rejections - 35 USC § 112

16. Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. Applicant's invention relies on luck and variations in the quality of the materials used to construct the biosensor, especially the cover and the substrate. In fact, the poorer the quality of the materials used for the cover and the substrate the better chance of success in making the claimed biosensor.

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Applicant has amended Claims 1 and 13

to state that the bottom surface of its cover is non-embossed. Support for the term "non-embossed" is found in the specification at page 1 lines 17-20, where it teaches that "According to the present invention, a biosensor is provided that forms a capillary channel between a cover and substrate, without the aid of a spacer or the additional manufacturing step of embossing either the cover or the substrate." [emphasis added] Additional support is found at page 2 lines 32-34, page 3 lines 3-8, page 12 lines 3-14 as well as Figures 1, 3, 6, and 8. (*Page 7 of the amendment.*)

Page 2, lines 32-34 of the specification states, "[t]he biosensor of the present invention includes a cover and a substrate, *both of which are formed without a predefined channel* and a reagent supported by the substrate [emphasis added]." So how is the channel formed? Page 3, lines 3-8 of the specification states,

"[t]he cover and the substrate inherently do not lie perfectly flat against one another, and therefore the capillary channel is created by default between unsealed portions of the cover and the substrate. The biosensor of the present invention takes advantage of surface irregularities of the cover and the substrate and the thickness of the reagent to form the capillary channel to move a liquid sample across the substrate and toward the reaction site [emphasis added]."

Thus, Applicant's invention relies on defects in the structure of the cover and the substrate and also random variation in reagent thickness to create the critical capillary channel, without which sample will not reach the reagent and be sensed by the sensing region of the biosensor. In order to make Applicant's invention one with ordinary skill in the art must rely on luck that there will be sufficient structural defects in the cover and substrate and sufficient random variations in the thickness of the reagent to create a capillary channel, such as shown in Figures 3-5 of the instant application. Inherently, with Applicant's invention no two biosensors will have the same capillary channel, if they will have capillary channels at all.

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Claims 20 and 21 are directed to a method of making the biosensor. The discussion above for claims 1-19 applies to claims 20 and 21 as well. Namely, the limitation in claim 20 of "the unsealed portion cooperating with the substrate to define a capillary channel extending across the reagent" relies on luck, defects in the materials from which the cover and substrate are made, and random variations in the thickness of the reagent.

Independent claims 22 and 31 have the same problems discussed above for claims 1-19. Claim 22 has the limitation "a non-preformed channel positioned between the unsealed portion of the bottom side and the cover, the channel extending across the reagent [Claim 22]." Although non-preformed, the channel exists, came into existence, through uncertainty. Similarly for independent claim 31.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

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do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

18. Claims 1-9, 12, 13, and 16-19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hodges et al. (US 6,174,420 B1).

Addressing Claim 1, Hodges et al. teach a biosensor comprising
a substrate, at least a portion being non-embossed (bottom element 13 in Figure 15);
a reagent positioned on the non-embossed portion of the substrate (col. 4, ll. 56-65); and
a cover (top element 13 in Figure 15) positioned on the substrate, the cover including a top side and a generally flat bottom side (i.e., having mostly parallel planar surfaces) being coupled to the substrate (top element 13 is coupled to bottom element 13 through spacers 1, middle element 13, and adhesive layers 3) to define a sealed portion and an unsealed portion (the sealed portion is the portion of top element 13 coupled to top element 1 through top adhesive layer 3), at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel across the reaction region (as seen in Figures 12 and 15 notches 16 cooperated with reaction cell 11 to provide a channel across the reaction region. Also note that sample enters the reaction cell by capillary action (col. 4, ll. 38-42)).

Applicant appears to argue that the new limitation of "a cover positioned on the substrate" should be interpreted to limit contact between the cover and substrate to direct physical contact. However, claim 12 provides for "an adhesive positioned *between* the cover and

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the substrate [emphasis added].” Thus, the claim language itself indicates a broader interpretation than argued for this limitation.

Addressing Claims 2-5 and 16, for a channel extending as claimed note openings 16 in relation to the channel in Figure 12.

Addressing Claim 6, the openings (elements 16 in Figure 12) are disrupted concave surfaces since they do not each have a smooth curvature, but instead have sharply joined edges.

Addressing Claim 7, two openings 16 may be seen in Figure 12.

Addressing Claims 8 and 19, as seen in Figure 12 the channel expands and then converges from the first opening toward the second opening.

Addressing Claim 9, for electrodes as claimed consider electrodes 13 in Figure 15.

Addressing Claim 12, for adhesive as claimed note layers 3 in Figure 15 and col. 4, ll. 26-37.

Addressing Claim 13, Hodges et al. teach a biosensor comprising
a substrate (bottom element 13 in Figure 15), at least a portion being non-embossed;
a reagent positioned on the non-embossed portion of the substrate (col. 4, ll. 56-65); and
a cover positioned on the substrate (top element 13 in Figure 15), the cover including a top side and a generally flat non-embossed bottom side (i.e., having mostly parallel planar

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surfaces), and an opening (openings 16 in Figure 12) extending between the top and bottom sides, the bottom side being coupled to the substrate (top element 13 is coupled to bottom element 13 through spacers 1, middle element 13, and adhesive layers 3) to define a sealed portion and an unsealed portion (the sealed portion is the portion of top element 13 coupled to top element 1 through top adhesive layer 3), at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel across the reaction region (as seen in Figures 12 and 15 notches 16 cooperated with reaction cell 11 to provide a channel across the reaction region. Also note that sample enters the reaction cell by capillary action (col. 4, ll. 38-42)).

Applicant appears to argue that the new limitation of “a cover positioned on the substrate” should be interpreted to limit contact between the cover and substrate to direct physical contact. However, claim 12 provides for “an adhesive positioned *between* the cover and the substrate [emphasis added].” Thus, the claim language itself indicates a broader interpretation than argued for this limitation.

Addressing Claim 17, for edges intersecting the openings as claimed see Figure 12.

Addressing Claim 18, for notches as claimed note openings 16, which include notches, in Figure 12.

Claim Rejections - 35 USC § 103

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,174,420 B1).

Hodges et al. teach a biosensor comprising

a substrate, at least a portion being non-embossed (bottom element 13 in Figure 15);

a reagent positioned on the non-embossed portion of the substrate (col. 4, ll. 56-65); and

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a cover (top element 13 in Figure 15) positioned on the substrate, the cover including a top side and a generally flat bottom side (i.e., having mostly parallel planar surfaces) being coupled to the substrate (top element 13 is coupled to bottom element 13 through spacers 1, middle element 13, and adhesive layers 3) to define a sealed portion and an unsealed portion (the sealed portion is the portion of top element 13 coupled to top element 1 through top adhesive layer 3), at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel across the reaction region (as seen in Figures 12 and 15 notches 16 cooperated with reaction cell 11 to provide a channel across the reaction region. Also note that sample enters the reaction cell by capillary action (col. 4, ll. 38-42)).

Applicant appears to argue that the new limitation of “a cover positioned on the substrate” should be interpreted to limit contact between the cover and substrate to direct physical contact. However, claim 12 provides for “an adhesive positioned *between* the cover and the substrate [emphasis added].” Thus, the claim language itself indicates a broader interpretation than argued for this limitation.

Hodges et al. do not mention the height of the channel, although a height in microns is implied because they teach that the channel is a capillary channel (col. 4, ll. 38-44) and that the electrodes, which form the top and bottom surfaces of the channel, are preferably less than 200 microns apart (col. 1, ll. 64-67). Barring evidence to the contrary, such as unexpected results, having the channel height less than 10 μm is a design choice. In particular, Applicant’s claimed biosensor is the biosensor taught by Hodges et al. scaled down in size to better accommodate a smaller sample volume.

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22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola
Alex Noguerola
12/05/03
Primary Examiner
TC 1753